REMARKS

Claims 1-8 are pending in this Application. The Examiner has indicated that claims 1-3 and 5-8 are allowed. Applicants thank the Examiner for the withdrawal of the previous rejections.

Applicants inadvertently neglected to amend the specification to address the Examiner's objection to the priority claim in the previous Office Action they have addressed the Examiner's concern in this response and apologize for the omission..

Claim 4 stands rejected and Applicant's address the rejection in this paper.

Claim 4 has been amended. Support for the amendment is found among other places at page 12, "Primer Directed Amplification Assay Methods".

CLAIM REJECTION UNDER 35 USC §102

Claim 4 stands rejected as being anticipated by Beard et al. which the Examiner characterizes as "the entire genome of type O FMDV". The Examiner contends the MPEP authorizes the Office to interpret "consisting essentially of" as the equivalent of "comprising" in this instance.

The Examiner cites MPEP §2163 and states:

"The specification does not define what is excluded by "consisting essentially of".

At the outset for clarity Applicants would point out that that the law does not require them in any literal way to define what is excluded by use of the term "consisting essentially of".

For example Applicants would point the Examiner to *PPG Indus. Inc. v. Guardian Indus. Corp.* which makes it clear that the entire purpose of the transitional phrase is to allow the drafter to encompass additional material that is not listed and therefore there is no duty thrust upon an applicant to recite what would be excluded.

> "By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to ***unlisted*** ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format". *PPG Indus. Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998)

Applicants note that claim 4 as amended is directed specifically to primers useful in the polymerase chain reaction.

A primer is defined at page 7 of the specification as:

> "an oligonucleotide (synthetic or occurring naturally), which is capable of acting as a point of initiation of nucleic acid synthesis or replication along a complementary strand when placed under conditions in which synthesis of a complementary stand is catalyzed by a polymerase"

It is respectfully submitted that the Examiner's citation of the "entire genome" cannot anticipate an "oligonucleotide". On that basis alone Applicants would respectfully request the rejection be withdrawn.

At page 12, Applicant's note in their specification that:

> "SEQ ID NOs:16-20 may be used as primers for use in primer-directed nucleic acid amplification for the detection of the presence of FMDV".

Again Applicants respectfully submit that the Examiner's citation of the "entire genome" cannot anticipate anything that can be used as a "primer for use in primer-directed nucleic acid amplification".

As to Applicant's previous statement that it is art recognized that PCR primers are intolerant of substantial changes, Applicants would direct the Examiner to their specification at page 13, line5-13 which states:

> Methods of PCR primer design are common and well-known in the art (Thein and Wallace, "The use of oligonucleotide as specific hybridization probes in the Diagnosis of Genetic Disorders", In *Human Genetic Diseases: A Practical Approach*, K. E. Davis Ed., (1986) pp 33-50; IRL: Herndon, VA; and Rychlik, W. (1993) In White, B. A. (ed.), Methods in Molecular Biology, Vol. 15, pp 31-39, PCR Protocols: Current Methods and Applications. Humania: Totowa, NJ)."

The references cited, *Thein and Wallace* and *Rychlik* (included herewith as **Exhibit A** and **Exhibit B** respectively), make it clear that PCR primer design is guided by well accepted principles and that the ordinarily skilled artisan, given Applicant's teaching of SEQ ID NOS: 16-20 as a starting point, can readily determine either empirically or by routine experimentation whether a modification which still allow the Applicant's sequence(s) to function as "a primer for use in PCR amplification for detection of FMDV". (that is whether the change is "substantial"or not).

For the Examiner's convenience Applicants provide additional evidence of the state of the art.

The Polymerase Chain Reaction in Current Protocols in Molecular Biology, *Ausubel,F.M., Brent,R., Kingston,R.E., Moore,D.D., Seidman,J.G., Smith,J.A. and Struhl,K.* (eds) (1989) pp. 15.1.7-15.1.9, John Wiley & Sons, New York. (**Exhibit C**)

Ausebel illustrates the point.

By way of example only Applicants would point the Examiner to *Ausebel* at page 15.1.7 second column which teaches that addition of even mismatched nucleotides at the 5' end of a primer sequence might still allow a given primer sequence to function in the polymerase chain reaction.

As noted in *Ausebel* at page 15.1.7 first column, second line under "Primer Selection" the design of PCR primers is often fraught with failure. Applicants have given the art primers which *work*, to only allow patent protection which allows the non-inventive copying of Applicant's invention by trivial modification is inequitable.

CONCLUSION

Given all of the foregoing Applicants respectfully request that the rejection over *Beard et al.* be withdrawn. and allowance of the above-referenced application is respectfully requested.

Respectfully submitted,

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